

**AMENDMENTS TO THE DRAWINGS:**

Please replace the originally-filed Figs. 1-2 with the new Figs. 1-2 including on two (2) attached drawing sheets marked REPLACEMENT SHEET. In new Fig. 2, one of the reference numbers 18 has been removed as it was redundant. Fig. 1 has not been changed.

Attachment: Two (2) sheets each marked REPLACEMENT SHEET including Figs. 1-2.

## REMARKS

Applicants submit this Amendment in reply to an Office Action mailed September 14, 2006.

By this Amendment, Applicants amend claims 12, 15, and 22, and add new claims 24-33. The originally-filed specification, drawings, and claims fully support the subject matter of amended claims 12, 15, and 22, and new claims 24-33. No new matter has been introduced.

Before entry of this Amendment, claims 12-23 were pending in this application. After entry of this Amendment, claims 12-33 are pending in this application. Claim 12 is the sole independent claim.

On page 2 of the Office Action, objection was made to the title. Applicants have amended the title as suggested by the Examiner. Accordingly, Applicants respectfully request withdrawal of the objection to the title.

On page 2 of the Office Action, Fig. 2 was objected to as including two reference number 18s. Applicants have removed the redundant reference number 18 from Fig. 2 in the attached drawing sheet of Fig. 2 marked REPLACEMENT SHEET. Accordingly, Applicants respectfully request withdrawal of the drawing objection. Applicants have also separated Figs. 1 and 2 such that they are now on separate sheets. Applicants thus submit two (2) sheets of replacement drawings.

On page 3 of the Office Action, objection was made to claim 22 for a typographical error. Applicants have amended claim 22 to correct this typographical error. Accordingly, Applicants respectfully request withdrawal of the claim objection.

On page 3 of the Office Action, claim 15 was rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. While Applicants do not necessarily agree that the term “substantially annular” is indefinite, solely in the interests of expediting the prosecution of this application, Applicants have amended claim 15 to remove the term substantially. Accordingly, Applicants respectfully request withdrawal of the Section 112, second paragraph rejection.

On pages 3-5 of the Office Action, claims 12-19 and 21-23 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0121496 A1 to Thiebault et al. (“Thiebault”). Applicants respectfully traverse this rejection.

Thiebault does not disclose the claimed invention. For example, as amended independent claim 12 recites a fluid transfer device including, among other aspects, “wherein the piercing mandrel includes a piercing portion configured to pierce the elastic stopper while the bead is being substantially disposed in the space.” Thiebault does not disclose at least this aspect of independent claim 12 either alone or in combination with the other aspects of independent claim 12.

According to its abstract, Thiebault discloses a transfer set 20 for transferring fluids from a first container, such as a conventional vial 22, to a second container, such as a conventional syringe (not shown). The transfer set 20 includes an integral tubular housing 40 having a tubular collar 46 surrounding the rim 26 of the vial 22, a radial portion sealingly engaging the stopper 30 in the vial 22, an integral tubular transfer member 52 and an outer tubular portion 50 surrounding at least the distal portion of the

tubular transfer member 52, a piercing member 42 within the tubular transfer member 52 and a closure releasably retaining the distal end of the piercing member 42.

Page 4 of the Office Action asserts that longitudinal channel 92, relatively sharp piercing end 84, central portion 36 of stopper 30, rim portion 26 of vial 22, and the space defined by tubular collar portion 46 of Thiebault respectively correspond to the piercing mandrel, piercing portion, elastic stopper, bead, and space of independent claim 12. Thiebault discloses piercing member 42, so Applicants will assume *arguendo* that this is what the Examiner intends to correspond to the piercing mandrel of independent claim 12. In any case, even assuming that all of the aforementioned relationships are true, Thiebault does not disclose the claimed invention because Thiebault does not disclose a “piercing mandrel [that] includes a piercing portion configured to pierce the elastic stopper while the bead is being substantially disposed in the space.”

Specifically, Thiebault discloses that piercing member 42 is not physically connected to tubular collar portion 46. Accordingly, during assembly, “the tubular collar portion 46 is received around the rim portion 26 of the vial 22” and the “free open end 46a of the collar portion 46 is then deformed radially into the reduced diameter neck portion 28 of vial 22 beneath the rim portion 26 of the vial.” (Paragraph [0028]). While all this occurs, piercing member 42 *does not* penetrate stopper 30, as this entire assembly of transfer set 20 installed on vial 22 is then transported to a health care worker. Only after the health care worker removes cap 44 and “the tip portion engages distal end 94 of the piercing member” is piercing member 42 driven “through the central portion 36 of the stopper 30, establishing fluid communication through the central

portion 36 through the channel 92 of the piercing member 42.” (Paragraphs [0028-0029]). Indeed, Thiebault teaches against a transfer device 20, “wherein the piercing mandrel includes a piercing portion configured to pierce the elastic stopper while the bead is being substantially disposed in the space.” Such a configuration would prevent Thiebault from attaching transfer set 20 to vial 22 without piercing member 42 piercing stopper 30 so as to allow it to be transported to a health care worker, and would thus impermissibly destroy Thiebault by rendering it unsatisfactory for its intended purpose. See In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Accordingly, for at least these reasons, Applicants respectfully request withdrawal of the Section 102(b) rejection based on Thiebault.

On pages 5-6 of the Office Action, claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Thiebault in view of U.S. Patent No. 5,358,501 to Meyer. Applicants respectfully traverse this rejection, at least because Meyer is not cited as remedying the aforementioned deficiencies of Thiebault. Accordingly, for at least these reasons, Applicants respectfully request withdrawal of the Section 103(a) rejection based on Thiebault and Meyer.

As noted above, Applicants have added claims 24-33. Applicants assert that each of claims 24-33 recite an aspect that is not disclosed by Thiebault. Accordingly, if a final Office Action is issued in this application, Applicants respectfully request that any rejection of the subject matter of each of claims 24-33 be individually addressed in the final Office Action.

Applicants further submit that each of claims 13-33 depends directly or indirectly from independent claim 12, and each is therefore allowable for at least the same

reasons that independent claim 12 is allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the references and therefore each is also separately patentable.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.


In discussing the claims in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

If there is any fee due in connection with the filing of this Amendment, please  
charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: January 25, 2007

By:   
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Attachment: Two (2) sheets marked REPLACEMENT SHEET including Figs. 1-2.